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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/579,846 | 05/25/2000 | Richard Wisniewski | 17882-733 | 8512 |

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| EXAMINER |
|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 3743 | |

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/579846 | Wisniewski | |
| | Examiner | Art Unit | |
| | Ford | 3743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☑ Responsive to communication(s) filed on 1-15-02

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☑ Claim(s) 2-18 is/are pending in the application. Note claim 1 has been canceled.

4a) Of the above claim(s) 4,5,10-17 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 2,3,6-9 and 18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)☑ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2+6

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other: _____

Applicant's election of Group I, a method of thawing biopharmaceutical, with traverse is acknowledged. Claims 2-11 and 18 are method claims. Claims 12-17 are apparatus claims.

A traverse based on the assertion that the "process cannot be performed by a materially different apparatus" is unconvincing. At the very least it is inconsistent with applicant's election of a patentably distinct species rather than applicant admitting all of the species are obvious variants. The method can be practiced by shaking the tank with the mechanism shown in Figure 1 or a huge number of materially different mechanisms described on page 13, line 7- page 14, line 26, among other places. This argument, in short, is completely unconvincing. The apparatus could heat and cool plastic by removing the biopharmaceutical and replacing it with plastic. There is respectfully submitted to be no real point of confusion here. Nakamura (5,524,706) is known to applicant from the prosecution of the parent application and applicant knows how plastic is freeze ~~thanked~~ thawed. The burden of examining what may be a hundred or more disclosed species is extremely burdensome notwithstanding counsel's allegations (unsubstantiated) that there is no severe burden.

The election of Figure 1 with traverse is acknowledged. This is taken to be an election of Figure 1, as shown, because of the failure of applicant to submit any proposed drawing correction to show any of the indeterminant number of variants. See Paper No. 3, page 4, lines 12-14 and page 5, lines 14-15. Claims 2, 3, 6, 7, 8, 9, 12, 13, 15, 16 and 18 have been identified as readable.

Both the election requirement between method and apparatus and the species requirement are deemed proper and the requirements are made Final.

An action on the merits as to claims 2, 3, 6-9 and 18 follows. The remainder of the claims are withdrawn as to non-elected inventions and species.

Please provide translations of DT 3047784 and WO 97/24152. They cannot be understood without English language translations. Please provide a copy of Quan article on the effects of vibration on Ice Contact melting. It appears to be more relevant than any of the other prior art cited by applicant, and must be provided in response to this office action.

On the other hand. the Examiner is surprised to see that the 1992 Wisniewski and Wu article "Large Scale Freezing and Thawing of Biopharmaceutical Drug Product" was not cited here or in the overseas PCT applications. It is, by far, the most relevant prior art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6-9 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over 1992 Wisniewski & Wu article "Large Scale

Freezing and Thawing of Biopharmaceutical Drug Product". See the entire document, but in particular read page 134, col. 1, lines 8-16 and lines 32-39.

The "shaker platform" discussed in lines 32-39 is deemed to be an "oscillatory driver" as claimed in claim 18. The heater used during the thawing cycle is discussed on page 135, col. 2, lines 21-32.

Regarding claims 2-3, shaker platforms are known to be harmonic and disharmonic and regarding claims 6-8 are known to come at these frequencies. Moreover the selected frequencies will be largely a function of the mechanical stresses the system will tolerate and hence subject to design choice absent some showing of unexpected results. The specification is devoid of any such showing.

Regarding claim 9, this is explicitly taught on page 134, col. 1, lines 32-34.

Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to claim 18 above, and further in view of Pepper.

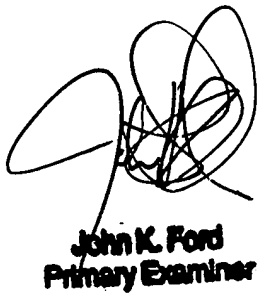
Pepper teaches 3.6 kHz and 20 kHz vibrators which are harmonic in nature. To have used these frequencies in the "shaker platform" of the prior art to dislodge the frozen product during the thawing cycle would have been obvious to speed the process and advantageously allow for greater throughput.

Claims 2, 3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to claim 18 above, and further in view of Baldus et al.

Baldus suggests that using oscillations (vibrations) of the heat exchanger surface of 10-50 Hz (preferably greater than 30Hz) with ("disharmonic") rest periods between than is extremely effective at shedding ice from a heat exchanger surface.

To have oscillated the prior art tank at frequencies of 30 Hz- 50 Hz with rest periods would have been obvious to quickly shed ice during the thawing cycle.

Any inquiry concerning this communication should be directed to John Ford at telephone number (703) 308-2636.




J. Ford

February 21, 2002